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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,946	12/06/2000	Robert C. Brunham	1038-1094MIS	7359

24223 7590 08/13/2004

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EXAMINER	
SWARTZ, RODNEY P	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 08/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/647,946	BRUNHAM, ROBERT C.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-35 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-35 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 9-5-01
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-35 are pending and under consideration.

Priority Statement

2. The priority statement at the beginning of the specification must be amended to reflect the entire priority claim. Currently, the statement only refers to the PCT application.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is meant by the phrase "The immunogenic of claim 8".

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-15 and 34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,235,290. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a nonreplicating vector comprising nucleotide sequences encoding fragments of MOMP.

7. Claims 1-15 and 34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,344,202. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a nonreplicating vector comprising nucleotide sequences encoding fragments of MOMP.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baxby et al (*Vaccine*, 10(1):8-9, 1992) in view of Dascher et al (*Microbial Pathogenesis*, 15:455-467, 1993) or Douglas et al (*J. Bacteriol.*, 178(19):5573-5578) or Kaul et al

(*Gene*, 87(1):97-104, 1990) and further in view of Anderson et al (*Inf. Immun.*, 64(8):3168-3173, 1996) and applicant's admission of record.

The instant claims are directed to *in vivo* administration of an immunogenic composition to a host, without restriction, comprising a nonreplicating vector.

Baxby et al is a review article teaching nonreplicating vectors (avipoxvirus) as recombinant vaccines, and providing references for the construction of various immunogenic compositions for *in vivo* administration (page 9). Baxby et al teach that nonreplicating avipox virus vectors provide significant advantages as recombinant vector based vaccines because the vectors should result in minimal or nonexistent side effects due to vaccination. Baxby et al do not teach a nucleotide sequence encoding *Chlamydia* MOMP or a MOMP fragment nor a plasmid (pcDNA3) expressing genes under the control of a cytomegalovirus promoter.

Dascher et al teaches the isolation of the entire *omp*1 gene from *C. psittaci* (page 456, section **Construction of MOMP expressing plasmids**). Dascher et al further teaches that: 1) MOMP is an immunodominant antigen thought to be the major target of neutralizing antibodies during chlamydial infection, 2) MOMP is a logical target of neutralizing antibodies since the protein constitutes approximately 60% of the outer membrane proteins, 3) recent experiments using the guinea pig as an animal model for *Chlamydial psittaci* strain GPIC infection have suggested a critical role for MOMP epitopes specified by its three dimensional structure in protective immunity (pages 455-456).

Douglas et al teaches purified MOMP sequences and promoters from *C. trachomatis* (Table 1; page 5573, section **DNA templates**).

Kaul et al teach chromosomal DNA isolated from purified *C. trachomatis* EB (page 98, section **DNA isolation and manipulation**).

Anderson et al teach a composition comprising a plasmid, pcDNA3, which encodes a gene expressed under the control of a cytomegalovirus promoter (Abstract; page 3168, section **Construction of pcDNA3/tetC**).

The instant claims are directed to nucleotide sequences encoding a region "which is at least one" of the conserved domains of a MOMP. The specification teaches that a nucleotide sequence which encodes a full-length MOMP protein encodes the various domains of the protein, e.g., conserved domains and variable domains (page 4, lines 6-35). Therefore, the full-length gene sequences taught by the cited references would comprise at least one of the conserved domains and at least one of the variable domains.

From the combined teachings of the cited references and applicant's admission of record, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

August 9, 2004